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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 10/800,372 | 03/12/2004 | Youngandh Chitre | A04P1024 | 8872 |
| 36802 | 7590 | 06/23/2006 | EXAMINER | |
| PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221 | | | JOHNSON, SHEVON ELIZABETH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/800,372 | Applicant(s) CHITRE ET AL. | |
| | Examiner Shevon E. Johnson | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Claims 8-14 are currently pending in this application. In regards to Applicant's arguments, see pgs. 4-6, filed 4/6/2006, with respect to the rejections of claims 8-12 and 14 under 35 USC § 102 as being anticipated by Brennen '119, Starksen '161, Pianca '320 and Mobin-Uddin '873 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made for claims 8-14 using references cited below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin, III (U.S. Patent No. 5,697,965) in view of Starksen (U.S. Patent No. 5,571,161).

In regards to claims 8 and 14, Griffin discloses a lead implant system comprising: a stylet 51 or a guide wire (not shown) being configured for slidable introduction into an elongated tubular lead body (col. 2, line 63 – col. 3, line 11; col. 4, lines 14-21 and 34-49; fig. 1). Griffin does not disclose a combined stylet and guide wire. However, Starksen teaches an elongated stylet 60 having an internal passage 62 extending longitudinally through the stylet; and a guide wire G that is slidably receivable in the longitudinally extending passage of the stylet (col. 5, lines 30-32; col. 5, lines 45-50; figs. 4 and 8B).

One having ordinary skill in the art would appreciate that Griffin and Starksen could be combined since they both teach a system and method for implanting leads or catheters in the heart for cardiac devices, and thus the references are analogous art. Therefore, it would have been obvious to anyone skilled in the art to have substituted the combined stylet and guide wire as disclosed by Starksen for the stylet as taught by Griffin, since such a modification would provide easy maneuvering of a lead or catheter to the desired implant location.

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4. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin, III (U.S. Patent No. 5,697,965) in view of Starksen (U.S. Patent No. 5,571,161) as applied to claim 8 above, and further in view of Spehr et al. (U.S. Patent No. 5,129,404), Haldeman et al. (U.S. Patent Pub. 20030191515) or Morgan et al. (U.S. Patent No. 6,944,506).

In regards to claims 9, 12 and 13, Griffin and Starksen in combination discloses a lead implant system substantially as claimed except for detailed description of the stylet and a lead with a thrusting region. However, Spehr (col. 3; fig. 2), Haldeman (pg. 3; fig. 3) and Morgan (col. 6; fig. 6) teach a stylet that is configured to be firmly engaged with a thrusting region of the lead to wedge the distal end of the lead. Additionally, wherein the stylet includes a ball member at its distal end and wherein the stylet is composed of stainless steel and the ball member is stainless steel welded to the distal end of the stylet.

Lacking any criticality, it would have been obvious to anyone skilled in the art to have substituted the distal end of the lead as taught by Griffin for the thrusting region of the lead as taught by Spehr, Haldeman or Morgan as a matter of obvious design choice, since such a modification would provide a bearing surface for engageably receiving the distal tip of the stylet thereby providing easy positioning of the lead or catheter at the desired implant location.

5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin, III (U.S. Patent No. 5,697,965) in view of Starksen (U.S. Patent No. 5,571,161) as applied to claim 8 above, and further in view of Samson et al. (Re. 33,911).

In regards to claims 10 and 11, Griffin and Starksen in combination discloses a lead implant system substantially as claimed except for detailed description of the guide wire. However, Samson teaches a guide wire 11 comprises: a proximal shaft 22; and an integral distal coil coaxial 24 with the proximal shaft and extending distally from the proximal shaft (col. 2, lines 13-16; fig. 1).

One having ordinary skill in the art would appreciate that Griffin, Starksen and Samson could be combined since they both teach a system and method for implanting leads or catheters in the heart for cardiac devices, and thus the references are analogous art. Lacking any criticality, it would have been obvious to anyone skilled in the art to have substituted the guide wire G as taught by Starksen for the guide

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wire 11 as taught by Samson as a matter of obvious design choice, since such a modification would provide the coil provides flexibility for maneuvering and the stiffer shaft for easy in positioning the guide wire at the desired implant location.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haldeman et al. (U.S. Patent Pub. 20030191515) or Morgan et al. (U.S. Patent No. 6,944,506) in view of Starksen (U.S. Patent No. 5,571,161).

In regards to claim 8, Haldeman (fig. 3) or Morgan (fig. 6) discloses a lead implant system comprising: a stylet 300/101 or a guide wire (not shown)/98 being configured for slidable introduction into an elongated tubular lead body. Neither, Haldeman or Morgan disclose a combined stylet and guide wire. However, Starksen teaches an elongated stylet 60 having an internal passage 62 extending longitudinally through the stylet; and a guide wire G that is slidably receivable in the longitudinally extending passage of the stylet (col. 5, lines 30-32; col. 5, lines 45-50; figs. 4 and 8B).

One having ordinary skill in the art would appreciate that Haldeman, Morgan and Starksen could be combined since they both teach a system and method for implanting leads or catheters in the heart for cardiac devices, and thus the references are analogous art. Therefore, it would have been obvious to anyone skilled in the art to have substituted the combined stylet and guide wire as disclosed by Starksen for the stylet as taught by Haldeman or Morgan, since such a modification would provide easy maneuvering of a lead or catheter to the desired implant location.

Citation of Relevant Prior Art

The prior art made of record and not relied upon but considered pertinent to applicant's disclosure includes Williams (U.S. Patent No. 4,498,482). Williams discloses a lead having a stylet comprising a taper neck for providing strain relief and a ball tip in order not to rupture the lead or a sensitive tissue.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766



Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766